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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,690	04/19/2004	Valerie Legrand	022290.0116C1US	9585

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,690	LEGRAND ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

In view of the Decision on Petition Under 37 CFR 1.78(a)(3) mailed 5/16/2007 dismissing the petition filed on 10/27/2006 to accept an unintentionally delayed claim under 35 U.S.C. § 120 for the benefit of priority to the prior-filed nonprovisional application set forth in the amendment filed 10/27/2006, the priority date for the instant application is considered to be the filing date of the instant application, or 4/19/2004, because a proper chain of priority has not been established.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 14, 15, 20 and 21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 5, 6, 11 and 12 of copending Application No. 10/492,129. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 14 of copending Application No. 10/492,129. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a microparticulate oral galenical form for delayed and controlled release at least one active principle, excluding perindopril. The galenical form comprises reservoir microcapsules which comprise a hydrophilic polymer A, a hydrophobic compound B, wherein the ratio of B/A is from 0.5 and 1.0. Compound B is selected from products that have a melting point between 40 and 90 °C. The particles have a diameter below 2000 microns. Accordingly, the claims are overlapping in scope and are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e. results in a claim which is not a proper process under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain trademark/trade names. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various materials to represent compound B and, accordingly, the identification / description is indefinite.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the microcapsules as defined in claim 1" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite the limitation of a microcapsule.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Legrand (FR 2,830,447, published 4/11/2003, whereby US 2005/0037077 is relied upon as equivalent for English language translation).

Legrand discloses microparticulate oral galenical form for the delayed and control release of at least one AP--excluding perindopril--this AP having an absorption window in vivo that is essentially limited to the upper parts of the gastrointestinal tract, said form being designed so as to guarantee its therapeutic efficacy by guaranteeing its absorption in vivo, and being characterized in that: the release of the AP is governed by two different triggering mechanisms, one being based on a variation in pH and the other allowing the release of the AP after a predetermined residence time in the stomach, and its dissolution behavior in vitro (determined as indicated in the European Pharmacopeia, 3rd edition, under the title: "Dissolution test for solid oral forms": type II dissolutest performed under SINK conditions, maintained at 37.degree. C. and agitated at 100 rpm) is such that: at a constant pH of 1.4, the dissolution profile includes a latency phase with a duration less than or equal to 5 hours, preferably of between 1 and 5 hours, and the change from pH 1.4 to pH 6.8, during the latency

phase, results in a release phase that starts without a latency period (paragraphs 0081 – 0085). The particles of AP each coated with at least one film, this coating film consisting of a composite material which comprises: at least one hydrophilic polymer A carrying groups that are ionized at neutral pH, and at least one hydrophobic compound B; and represents a mass fraction (% by weight, based on the total mass of the microcapsules) of ≤ 40; and have a diameter below 2000 microns, preferably of between 200 and 800 microns and particularly preferably of between 200 and 600 microns, characterized in that their coating film consists of a composite based on A and B in which the weight ratio B/A is between 0.2 and 1.5, preferably between 0.5 and 1, and the hydrophobic compound B is selected from products that are crystalline in the solid state and have a melting point T_{fB} such that $T_{fB} \leq 40$.degree °C (paragraphs 0088 – 0096). Hydrophilic polymer A may be methacrylic acid, cellulose derivatives, etc. (paragraph 0097 – 0101). Compound B may be vegetable waxes, etc. (paragraph 0102 – 0106). at a constant pH of 1.4, the controlled release phase following the latency phase is such that the release time for 50% by weight of the AP ($t_{1/2}$) is defined as follows (in hours): $0.5 \leq t_{1/2} \leq 20$ (paragraphs 0123 – 0125). Preferably the AP is deposited on a neutral core, which may be sucrose and/or dextrose and/or lactose, or it can consist of a cellulose microsphere (paragraph 0132). The AP may be the AP is selected from the following compounds: metformin, acetylsalicylic acid, amoxicillin, pentoxifyllin, prazosin, acyclovir, nifedipine, diltiazem, naproxen, etc. (paragraph 0142). The microparticulate oral galenical form according to

the invention can be a tablet, advantageously a tablet that disperses in the mouth, a powder or a gelatin capsule (paragraph 0143).

Claims 1 – 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishibashi *et al.* (EP 1 101 490).

Ishibashi discloses a preparation in which a core material containing a medicinal substance coated with a mixed film of hydrophobic organic compound-enteric polymer, which has a unique releasing behavior that the preparation releases no medicinal substance in an acidic solution but releases a medicinal substance quickly in a neutral or basic solution after a certain period of time (lag-time). The lag-time can be controlled by changing a coating amount of film and a ratio of an amount of the hydrophobic organic compound to an amount of the enteric polymer (page 3, lines 1-9). The hydrophobic organic compound may be stearic acid, laurlc acid, myristic acid, palmitic acid, behenic acid... hydrogenated castor oil, hydrogenated coconut oil or beef tallow, etc.; and the enteric cellulose derivative is hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, hydroxymethylethylcellulose phthalate, cellulose acetate phthalate, etc. including various copolymers (page 3, lines 25 – 45). The ratio of organic compound to enteric polymer is from 30:70 to 80:20 (page 3, line 47), and the coating comprises 20 - 100% by weight of the formulation (page 3, line 49). The core article of the present invention is consisting of a medicinal substance alone, or is consisting of a medicinal substance and various additives for preparations usually employed in the art. Examples of the formulation include a tablet,

a capsule and the like, as well as particles such as a grain and a qranule. Among them, a grain, a granule or a tablet are particularly preferable (page 6, line 57). Examples of inert carriers include, for instance, crystallines of sugars or inorganic salts such as crystalline of lactose, microcrystalline cellulose, crystalline of sodium chloride, a spherical granulated material (such as the spherical granulated material of crystalline cellulose (available from Asahi Chemical Industry Co., Ltd.; Trade-name: Avicel SP), the spherical granulated material of crystalline *cellulose* and lactose ~available from Freund Industrial Co., Ltd.; Trade-name: Nonpareil NP-5, and Nonpareil NP-7), the spherical granulated material of refined sugar (available from Freund Industrial Co., Ltd., Trade, name: Nonpareil-lO3),. the spherical granulated material of lactose (page , lines). Note: Avicel SP, for example, inherently has a diameter of 150-250 μm, which is within the claimed range of particle size (See US 5824339, column 4, lines 9-10 for evidence of inherency). The medicinal substance may be a variety of drugs, such as ibuprofen, amoxicillin, etc. (see page 7). Regarding the dissolution properties, the lag-time can be determined as the time until a start of releasing a medicinal substance to the second fluid (pH 6.8) of the disintegration test by a person skilled in the art, the mixed ratio and the coated amount to obtain the desired lag-time are easily determined by preparing preparations having various mixed ratios and coating ratios. In this case, it is preferable not to release the medicinal substance for 5 hours in the first fluid (pH 1.2) of the disintegration test. The lag-time may be freely designed according to the desired site delivered a medicinal substance. To obtain a validity of a preparation in the present invention, it is required not releasing the medicinal substance for at least 2

hours in the second fluid (pH 6.8) of the disintegration test. Namely, the lag-time is preferably at least 2 hours, more preferably at least 3 hours (page 6, lines 6 – 20). It is noted that the dissolution test was measured according the Japanese Pharmacopeia, rather than the European Pharmacopeia under SINK conditions, as recited in claim 1. However, the formulation of Ishibashi discloses all of the same material components as those instantly claimed (i.e. core granule (of inherently the same core size) and hydrophobic compound/enteric coating in the same ratios and weight percentages), and thus would inherently have the same dissolution profile. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. Limitations such as the dissolution profile tested under specific conditions are descriptive and thus would be an inherent property of the claimed composition. In the absence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

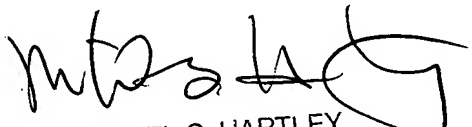
No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER